

REMARKS/ARGUMENTS

With this amendment, claims 1, 3-7, 9, and 20-21 are under examination. New claim 58 is added. Claims 6 and 9 are cancelled without prejudice to subsequent revival. For convenience, the Examiner's rejections are addressed in the order presented in the July 2, 2003 Office Action.

I. Status of the claims

Claim 1 is amended to recite an isolated nucleic acid encoding a tumor suppressor polypeptide p33ING2 that has at least 90% identity to the nucleotide sequence of SEQ ID NO:2. Support for this amendment is found throughout the specification, for example, at page 17, line 23. This amendment adds no new matter.

Claim 1 is also amended to recite an isolated nucleic acid encoding a p33ING3 polypeptide that functions as a tumor suppressor. Support for this amendment is found throughout the specification, for example, at page 8, line 32 through page 9, line 3; page 10, lines 1-11; and at page 44, lines 31-33. This amendment adds no new matter.

New claim 58 is added and recites an isolated nucleic acid encoding a tumor suppressor polypeptide p33ING2 that has at least 95% identity to the nucleotide sequence of SEQ ID NO:2. Support for this amendment is found throughout the specification, for example, at page 17, line 23. This amendment adds no new matter.

II. Rejections under 35 U.S.C. §112, first paragraph, written description

Claims 1, 5-7, 9, and 20-21 are rejected under 35 U.S.C. §112, first paragraph as allegedly containing subject matter that was not described in specification. The Office Action points out that the purpose of the written description requirement is to demonstrate that the inventors had possession of the claimed invention at the time of filing. The Office Action also points out that, to provide adequate written description of a genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The characteristics include complete or partial structure, other physical and/or chemical properties, functional characteristics

when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. The Office Action alleges that the specification lacks sufficient identifying characteristics and does not provide adequate written description of the claimed genus.

To the extent the rejection applies to the claims as amended, Applicants respectfully traverse the rejection. The claims are directed to a genus of nucleic acids that encode p33ING2 polypeptides that function as tumor suppressors and that are at least 90% identical to a reference sequence (*i.e.*, SEQ ID NO:2). Applicants submit that the specification provides distinguishing identifying characteristics for the claimed genus and provides a representative number of species encompassed by the claimed genus.

First, the claimed nucleic acids all share at least 90% identity to a reference sequence, *i.e.*, a structural characteristic of the claimed genus. Those of skill are able to determine percent identity shared by two nucleic acid sequences, using well known computer programs and web sites for sequence analysis. Second, the claimed nucleic acids encode proteins that function as tumor suppressors. Assays to identify proteins that function as tumor suppressors are found through out the specification. As described in the specification, a suspected tumor suppressor is expressed in a transformed cell line and assayed for phenotypes that indicate changes in cell proliferation. For example, tumor cells fail to grow on soft agar when transformed with a tumor suppressor (page 40, line 32 through page 41, line 19); tumor cells exhibit contact inhibition when transformed with a tumor suppressor (page 41, line 21 through page 42, line 14); tumor cells lose serum independence when transformed with a tumor suppressor (page 42, lines 16-29); tumor cells fail to express specific markers when transformed with a tumor suppressor (page 42, line 31 through page 43, line 17); tumor cells decrease invasiveness on Matrigel when transformed with a tumor suppressor (page 43, line 10 through page 44, line 2); tumor cells exhibit apoptosis when transformed with a tumor suppressor (page 44, lines 4-21); and tumor cells arrest in G₀/G₁ when transformed with a tumor suppressor. Specific examples of some of these assays are also provided in Examples VII-IX at pages 67-68.

The specification also provides a representative number of species that belong to the claimed genus. Polymorphic variants of the p33ING polypeptides are described at page 9,

lines 4-8. The polymorphic variants include a Thr to Ser substitution at amino acid position 11, a Leu to Ile substitution at amino acid position 101, and an Ala to Gly substitution at amino acid position 251. The claimed genus encompasses nucleic acids that encode these polymorphic variants of the p33ING2 tumor suppressor protein.

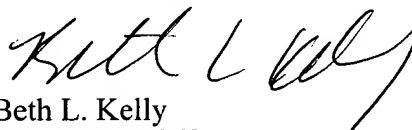
In view of the above amendments and remarks, Applicants respectfully request that the rejection under 35 U.S.C. §112, first paragraph be withdrawn.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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